




Select Agent Program Workshop

November 2012

Agricultural Select Agent Program (USDA/APHIS)

CDC Select Agent Program (HHS/CDC)

Bioterrorism Risk Assessment Group (FBI/CJIS)

APHIS

CDC

Revised APHIS/CDC Form 1

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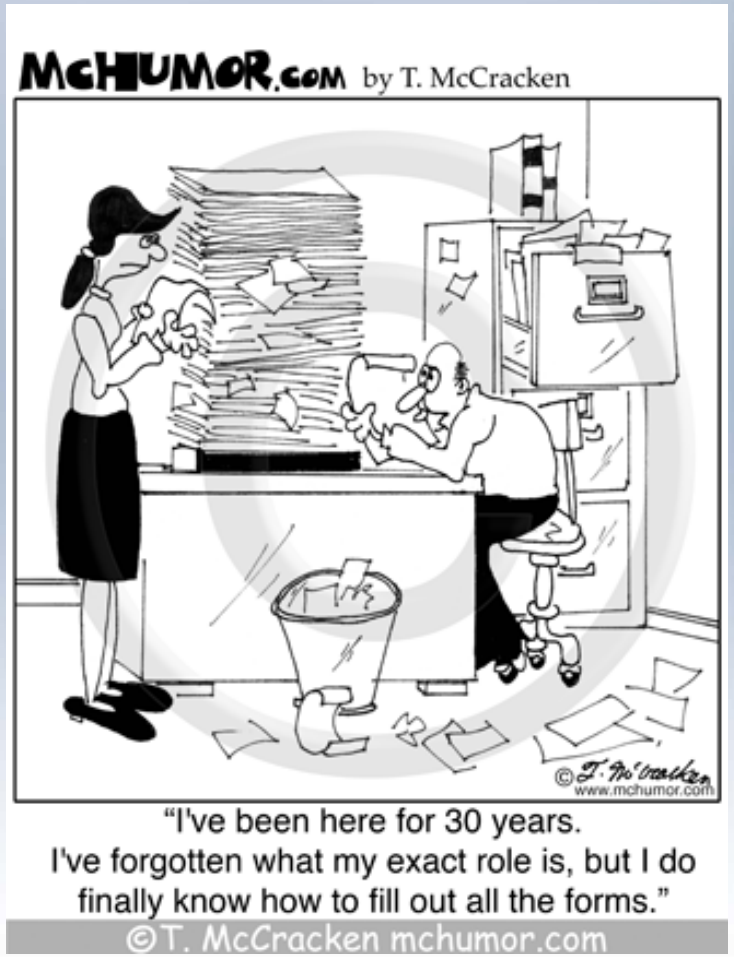
Reasons for Revised APHIS/CDC Form 1

- Capture additional information required in the 2012 Final Rule
  - Examples: new Tier 1 requirements, new restricted experiment definition
- Streamline amendment process



When to use the revised APHIS/CDC Form 1?

	Days post publication of revised "current" APHIS/CDC Form 1 to www.selectagents.gov		
TYPE OF SUBMISSION	Received 0 – 29 days	Received 30 – 179 days	Received on or after 180 days(3)
New application or amendment	Current(1) or previous(2)	Current	Current
Update to pending application or amendment	Same version of Form 1 as original application, amendment, or renewal amendment	Same version of Form 1 as original application, amendment, or renewal amendment	Current

(1) Current = Form 1 with OMB expiration date of XX/XX/XXXX.
(2) Previous = Form 1 with OMB expiration date of 10/31/2014.
(3) The Federal Select Agent Program will not support the previous Form 1 after 179 days post publication. For any application or amendment on the previous Form 1 pending at 180 days post publication, the application, amendment, or renewal amendment will be required to resubmit on the current Form 1 .

Note: Renewal amendments consisting of a complete APHIS/CDC Form 1 may be submitted on the previous form until 89 days post publication.

Note: The previous version of Form 1 may not be used for any **new** amendment or renewal amendment once the current Form 1 has been used **even if** the timeline in the table would permit.

Broad Overview of Revisions

- **Section 1**:
  - A- Includes Responsible Official (RO)/ Alternate Responsible Official (ARO)/Owners/Controllers information form security risk assessment (no longer on Section 4)
  - B- Previous Section 2
  - C- New entity abstract
- **Section 2**: RO attestations (initial and sign)
- **Section 3**: No laboratory or Principal Investigator (PI) information
- **Section 4**: Separated into A, B, C by role
  - Will not include all personnel
  - Section 1: RO/ARO/Owner/Controller, Section 7: PI
- **Section 5**: Entity-wide information
  - A- Entity-wide security and incident response
  - B- Biosafety
  - C- Inspector entry requirements
- **Section 6**: Suite/Room specific information (security and physical)
- **Section 7**: PI specific information; work specific attachments (toxin, animal, BSL3-Ag, etc.)

Type of Information

Entity-wide	Suite/Room Specific	PI/Work Specific
Section 1	Section 6	Section 7 (with attachments)
Section 2		
Section 3		
Section 4		
Section 5		

“Smart” Form

The Basics

- APHIS/CDC Form 1 or section of the form to be used **must be saved** before information is added
- Ensure that you have the latest version of Adobe Acrobat before downloading

Smart Form

- Text boxes and tables will grow as needed
- Can add additional AROs, Owners/Controllers, PIs
- Drop down boxes with selections
- Add additional Sections 6 and 7 and Attachments

Headers

- Header information changes
  - Sections 1–5 (new registration/amendment/renewal, entity name, date)
  - Section 6 (adds Building/Suite or Room)
  - Section 7 (no Building/Suite or Room, adds PI)
  - Section 7 Attachments (includes PI, adds laboratory safety level for 1-5)

Managing APHIS/CDC Form 1 and changes

Complete Form 1 for renewal and application

Individual section(s) of Form 1 for amendments

Options for organization (version control)

- Name and save file with date, amendment #, PI name, room #, etc.
- Modify saved files for future use
- Maintain separate files
  - Entity-wide information (Sections 1-5)
  - Building/suite or room information (Section 6)
  - PIs (Section 7), more frequently update PI work objectives, strain/serotype table, attachments, etc.

Records

- Some amendments only require submission of a cover letter.
- **Partial** Sections 3, 4, 7A: emphasis on receipt of change
- **Entity still must maintain complete records** (3 years)

Revised APHIS/CDC Form 1

- Presentation does not include all Form 1 sections or questions
- Instructions available in a separate document
- Will be posted on www.selectagents.gov

Section 1 - Entity Information

USDA

APPLICATION FOR REGISTRATION FOR POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 1)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE XX/XX/XXXX

Section 1A – Entity Information			
This submission is: ☐ A new registration ☐ An update to an existing registration ☐ A renewal			Date:
ENTITY INFORMATION			
Entity Application Number (e.g., CDC030001):			
Current Registration Number (e.g., A00000000-0000):			
Entity Name:			
Physical Address (NOT a post office box):	City:	State:	Zip Code:
Additional Physical Address(es):			
Type of Entity: ☐ Academic (Private) ☐ Government (Federal)	☐ Academic (State) ☐ Government (State/Local)	☐ Commercial (Profit) ☐ Private (Non-Profit)	

Section 1A: Personnel

RESPONSIBLE OFFICIAL INFORMATION			
Last Name:	First Name:	DOJ Number:	Date of Birth:
Business E-mail Address:	Title (e.g., Biosafety Officer):		Tier 1 Access ☐
Business Telephone #:	Business Fax #:	Emergency Telephone #:	
Mailing Address (NOT a post office box):	City:	State:	Zip Code:

ALTERNATE RESPONSIBLE OFFICIAL INFORMATION			
Last Name:	First Name:	DOJ Number:	Date of Birth:
Business E-mail Address:	Title (e.g., Biosafety Officer):		Tier 1 Access ☐
Business Telephone #:	Business Fax #:	Emergency Telephone #:	
Mailing Address (NOT a post office box):	City:	State:	Zip Code:
Last Name:	First Name:	DOJ Number:	Date of Birth:
Business E-mail Address:	Title (e.g., Biosafety Officer):		Tier 1 Access ☐
Business Telephone #:	Business Fax #:	Emergency Telephone #:	
Mailing Address (NOT a post office box):	City:	State:	Zip Code:

OWNER / CONTROLLER INFORMATION (If Applicable)		
Last Name:	First Name:	
DOJ Number:	Date of Birth:	Tier 1 Access ☐
Last Name:	First Name:	
DOJ Number:	Date of Birth:	Tier 1 Access ☐

Section 2:
RO Certification of Personnel and Facility Activities

- New section
- RO certifies many of the current Form 1 “check yes” questions
- RO must complete (not ARO)
- Submit for: New application, appointment of new RO, renewal

Section 2 – Responsible Official Certification of Personnel and Facility Activities

I certify that the following requirements are in effect and contain all information required by the Select Agent regulations [7 CFR 331, 9 CFR 121, and 42 CFR 73] (**initial each line**):

Security, Biosafety and Incident Response

_____ There is a written, **site-specific** security plan designed according to a **site-specific risk assessment that provides graded protection** in accordance with the risk of the select agent and/or toxin.

_____ There is a written, **agent-specific, and site-specific** biosafety plan commensurate with the risk of the select agent and/or toxin that contains sufficient information and documentation to describe the biosafety and containment procedures.

_____ There is a written, **site-specific** incident response plan commensurate with the hazards of the select agent and/or toxin that fully describe the entity’s response procedures to include the theft, loss or release of a select agent and/or toxin, inventory discrepancies, security breaches, natural disasters and emergencies.

Section 3 – Select Agents and Toxins

Section 3 – Select Agents and Toxins		
HHS Agents and Toxins (Check if possessed)	Overlap Agents and Toxins (Check if possessed)	USDA Agents and Toxins (Check if possessed)
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐

- Select agents, toxins, regulated nucleic acids
  - No building/room
  - No PI
- Drop down boxes with select agent/toxin names

Section 3 - Possession of BSAT

Check if Select Agent/Toxin Possessed

- For new applications this box will not be checked for any agent or toxin as the entity is not authorized to possess select agent and/or toxin without an approved registration certificate.
- The entity will need to submit an updated Section 3 and Section 7B **within 7 days** of acquisition which indicates possessed agents. See amendment guidance for how to update this information upon possession of select agent and/or toxin.

Additional Information

- **Section 3 must include regulated nucleic acids listed above if you possess, transfer and/or use extracted and isolated nucleic acids that meet the requirements defined in section 3(c) and section 4(c) of 42 C.F.R Part 73, 9 C.F.R Part 121, and 7 C.F.R Part 331.**
- **The registration of intact, live agent is sufficient to cover the genomic material in that agent as long as it is not extracted and isolated for further testing or research purposes.**
- **For additional information regarding regulated nucleic acids, refer to the Synthetic Genomics Guidance Document.**

Section 3
Changes to Select Agent and Toxin List

- Addition of SARS-CoV, Lujo, Chapare viruses
- Removal of biological select agents and toxins (BSAT)
- Taxonomic changes

Tier 1 Select Agents and Toxins		
HHS Agents and Toxins	**Overlap Agents**	**USDA Agents**
Botulinum neurotoxins Botulinum neurotoxin producing species of *Clostridium* Ebola virus *Francisella tularensis* Marburg virus Variola major virus (Smallpox virus) Variola minor virus (Alastrim) *Yersinia pestis*	*Bacillus anthracis* *Burkholderia mallei* *Burkholderia pseudomallei*	Foot-And-Mouth Disease virus Rinderpest virus

Section 3
Changes to Select Agent and Toxin List

- Highly Pathogenic Avian Influenza has been updated to **Avian influenza virus** on the USDA Select Agent and Toxin List

- All Avian influenza virus strains are considered select agents ***unless proven to be low pathogenic*** Avian influenza virus

Section 3
Changes to Select Agent and Toxin List

- Virulent Newcastle Disease virus has been updated to **Newcastle Disease virus** on the USDA Select Agent and Toxin List

- All Newcastle Disease Viruses are select agents unless shown to have an intracerebral pathogenicity index (ICPI) less than 0.7

Registration of Regulated Nucleic Acids (SA GRAM 09/12/12)

- Viral nucleic acids (+ ss RNA viruses) and recombinant/synthetic nucleic acids encoding functional toxin are also regulated as "select agents"
- Entities must register these regulated nucleic acids to possess, use or transfer these select agents
- To amend registration:
  - Cover letter
  - Section 3 (partial)
  - Section 6 [if new room(s)]
  - Section 7 (describe work)

HHS Select Agent and Toxin Regulated Nucleic Acids
Genomic material – Eastern Equine Encephalitis virus
Genomic material – Kyasanur Forest disease virus
Genomic material – Omsk Hemorrhagic Fever virus
Genomic material – SARS–associated coronavirus (SARS-CoV)
Genomic material – Tick-borne encephalitis virus, Far Eastern subtype
Genomic material – Tick-borne encephalitis virus, Siberian subtype
Recombinant/synthetic nucleic acids encoding Abrin
Recombinant/synthetic nucleic acids encoding Botulinum neurotoxin
Recombinant/synthetic nucleic acids encoding Conotoxins
Recombinant/synthetic nucleic acids encoding Diacetoxyscirpenol
Recombinant/synthetic nucleic acids encoding Ricin
Recombinant/synthetic nucleic acids encoding Saxitoxin
Recombinant/synthetic nucleic acids encoding Staphylococcal enterotoxin A
Recombinant/synthetic nucleic acids encoding Staphylococcal enterotoxin B
Recombinant/synthetic nucleic acids encoding Staphylococcal enterotoxin C
Recombinant/synthetic nucleic acids encoding Staphylococcal enterotoxin D
Recombinant/synthetic nucleic acids encoding Staphylococcal enterotoxin E
Recombinant/synthetic nucleic acids encoding T-2 toxin
Recombinant/synthetic nucleic acids encoding Tetrodotoxin
Overlap Select Agent Regulated Nucleic Acids
Genomic material – Venezuelan Equine Encephalitis virus
USDA Veterinary Services (VS) Select Agent Regulated Nucleic Acids
Genomic material – Classical Swine Fever virus
Genomic material – Foot-And-Mouth Disease virus
Genomic material – Swine Vesicular Disease virus

Section 4: Personnel Overview

- New sections A, B, C based on the individual's role
- Tier 1 Access boxes
- **Section 4A:** Laboratorians and Animal Care Staff – no major change to table, still designate role and supervising PI

Please refer to the definition below when specifying a Laboratorian or Animal Care Staff.

- **Laboratorians and Animal Care Staff–** an individual who performs any of the work listed in a Section 7C, Question 1 and manipulates select agents or toxins or handles select agent infected animals, plant hosts or select agent contaminated hazardous waste (including animal bedding).

- **Section 4B:** Support Staff roles (e.g., Safety), but no supervising PI

Please refer to the definition below when specifying Support Staff:

- **Support Staff** – an individual who provides an indirect service in support of the direct work with select agents or toxins, does not work with select agents or toxins or select agent infected animals, bedding or plant hosts, but could potentially gain access to select agents/toxins.

Section 4: Personnel Overview

- **Section 4C:** Unescorted Visitors
- Typically visiting scientists that have access approval at a different entity
- Not to be confused with **escorted** visitors for maintenance, cleaning, BSC certifications, etc. that are not included on registration and will not have access to select agent or toxin

Unescorted Visitor – an individual who has access approval at a registered entity (the "home" entity) other than yours (the "host entity") and will temporarily work with, or have access to, select agents or toxins, and receive site-specific training, at your registered entity. More detailed information for visitors can be found on the NSAR website located at http://www.selectagents.gov/FAQ_SecurityRiskAssessments.html#sec1q5 under the Visiting Scientist section.

Note: Visitors should only be listed on Section 4C.

Section 4A – Laboratorians and Animal Care Staff

Tier 1 Access	Last Name	First Name	DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Role	Supervising Principal Investigator
X	Jones	Mary		01/01/1970	Laboratorian	John Smith
X	Johnson	Bill		02/02/1980	Laboratorian	John Smith
X	Taylor	John		03/03/1985	Animal Care Staff	John Smith
	White	Doug		04/01/1990	Animal Care Staff	J. Clark

Section 4B – Support Staff

Tier 1 Access	Last Name	First Name	DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Role
X	Williams	Sue		12/22/1945	Maintenance
X	Anderson	James		03/03/1974	Safety

Section 4C – Unescorted Visitors

Tier 1 Access	Last Name	First Name	HOME DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Supervising PI
X	Johnson	Christy	C-CJ-123456	01/01/1975	John Smith
X	Simmons	Andrew	C-AS-654321	02/02/1979	John Smith

Section 5 – Entity-Wide Information

- All Section 5 questions apply to entity as a whole
  - 5A: Security and Incident Response
  - 5B: Biosafety
  - 5C: Entry requirements for Inspections
- Answer questions to provide entity-wide “big picture”
  - Example: Section 5A, Question 8 – Does the entity transport select agent and/or toxin outside of registered areas?
- Rationale:
  - To prevent this information from being submitted multiple times for multiple PIs
  - To prevent entity-wide information from being submitted when changes to this information are not requested

Section 5A - Entity-Wide Security & Incident Response

This submission is: ☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:		Date:

Section 5A – Entity-Wide Security Assessment and Incident Response

4. Insider risk assessment
   a. As a condition of granting unescorted access, the entity, or another organization on behalf of the entity, verifies (check all that apply):
      - ☐ Educational background
      - ☐ Previous work references
      - ☐ Criminal history (beyond the security risk assessment approved by the Federal Select Agent Program)
      - ☐ Other _____
      - ☐ None
   b. Does the entity have policies and procedures for self and peer reporting? Yes☐ No☐
   c. Does the entity have additional requirements for personnel suitability to retain access to select agents or toxins? Yes☐ No☐

5. Natural hazards
   a. Is the entity located in any of the following hazard zones?
      - ☐ Flood/flood zone
      - ☐ Hurricane
      - ☐ Tornado
      - ☐ Other_____
      - ☐ Earthquake (as defined by USGS)
      - ☐ Wildfire
      - ☐ Tsunami
   b. In the event of a natural disaster with warning, the entity will (check all that apply):
      - ☐ Secure the select agent and/or toxin in place.
      - ☐ Transfer the select agent and/or toxin to an alternate registered location or entity.
      - ☐ Destroy the select agent and/or toxin.
      - ☐ Other _____

Section 5A - Entity-Wide Security & Incident Response

This submission is: ☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:		Date:

Section 5A – Entity-Wide Security Assessment and Incident Response

7. Shipping/Receiving
   a. Does the entity have a centralized receiving area? Yes ☐ No ☐
   b. Are all personnel who ship or receive select agent and/or toxin shipments Security Risk Assessment (SRA) approved? Yes ☐ No ☐
   c. Are select agent and/or toxin shipments stored in a registered and secured area prior to distribution to the Principal Investigators (PIs)? Yes ☐ No ☐

8. Does the entity transport select agent and/or toxin outside of registered area(s)? Yes ☐ No ☐
   If yes, does the security plan address transport of select agent and/or toxin material
   a. through non-registered areas? Yes ☐ No ☐
   b. during intra-entity transfers using chain of custody documentation? Yes ☐ No ☐

9. Has a response time for local law, guard force or other designated responders been determined? Yes ☐ No ☐

10. Is permission required to conduct select agent and/or toxin work after established work hours? Yes ☐ No ☐
    If yes, who grants permission?
    ☐ RO/ARO
    ☐ PI
    ☐ Other _____

ROLE – please do not personalize with names

Section 5B - Entity-Wide Biosafety

Section 5B – Entity-Wide Biosafety/Biocontainment

1. Describe the program or expertise used to develop and implement the biosafety and biocontainment procedures described in the site-specific biosafety or biocontainment plan. Add additional sheets as needed.

2. Laboratory personnel must demonstrate proficiency in laboratory procedures prior to working with select agents and/or toxins. Yes☐ No☐

3. Appropriate Personal Protective Equipment (PPE) for the select agent and/or toxin and the work performed is required. Yes☐ No☐

4. Individuals with access to Tier 1 select agent and/or toxin are enrolled in an occupational health program. Yes☐ No☐

5. Laboratory personnel with access to non Tier 1 select agent and/or toxin are enrolled in an occupational health program as appropriate. Yes☐ No☐

6. There are policies for the safe handling of sharps. Yes☐ No☐

7. There is a spill protocol in place appropriate to the select agent and/or toxin risk. Yes☐ No☐

8. There is an effective, integrated pest management program in place. Yes☐ No☐

Section 5C – Entry Requirements for Federal Select Agent Program Inspectors

This submission is: ☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:		Date:

Section 5C – Entry Requirements for Federal Select Agent Program Inspectors

1. Describe procedures for entry to the facility, such as gate location, visitor reception area, and parking for inspectors performing a site visit. Add additional sheets as needed.

2. Identification requirements:
   - ☐ Government ID
   - ☐ Other ID (describe) _____

Revised Policy for Inspector IDs:
SA GRAM 07/19/12

3. Are there security clearance requirements? Yes☐ No☐
   If yes, check all that apply.
   - ☐ Exchange of security clearance documentation
     Describe _____
   - ☐ Completion of entity specific security documentation
     Describe _____

4. Is respiratory protection required? Yes☐ No☐
   a. Documentation of medical clearance for respirator use required. Yes☐ No☐
   b. List required respirators (check all that apply):
      - ☐ N95
      - ☐ N100
      - ☐ PAPR: If required, will the entity provide PAPRs? Yes☐ No☐
      - ☐ Other _____

Section 6 – Building/Suite or Room Information

- All information in Section 6 (6A and 6B) for **each** suite/room
  - If all information is identical, multiple suites/rooms can be submitted on one Section 6
- **Security information (6A)** is organized from outside the building working in to the select agent/toxin
- **Physical information (6B)** to describe biosafety level and features of each laboratory suite/room
- Storage only – complete 6A and provide floor plan
- Rationale:
  - To prevent suite/room info from being submitted multiple times for multiple PIs when shared
  - To avoid submitting suite/room info when a PI is replaced or updated

Suite Designations

- Register suites as appropriate
- Laboratories and animal holding rooms within a suite must have the same biosafety number
  - Example: BSL3, ABSL3, NIHBL3
  - Not BSL3 and BSL2
- Section 7A: **Suite Legend** at bottom of table for suite definition (specific rooms that make up the suite)

Section 6A – Building and Suite/Room Specific Security

This submission is: ☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:		Date:
Building/Suite or Room:		

Section 6A – Building and Suite/Room Specific Security

1. Will this suite/room be used for Tier 1 select agent and/or toxin? Yes ☐ No ☐

2. Perimeter security measures outside the building (check all that apply):
   - ☐ Security lighting
   - ☐ Bars/security film on windows
   - ☐ Exterior intrusion detection system
   - ☐ Perimeter fence
   - ☐ Roving guards
   - ☐ Video surveillance of all access points
   - ☐ Vehicle screening
   - ☐ Other _____
   - ☐ None

3. Access to building(s) or other area(s) housing the suite/room is controlled by (check all that apply):
   - ☐ Lock and key
   - ☐ Biometric system
   - ☐ Other _____
   - ☐ None
   - ☐ Card access system
   - ☐ Card access system w/ PIN
   - ☐ Guards

Section 6B – Suite/Room Physical Information

This submission is: ☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:		Date:
Building/Suite or Room:		

Section 6B – Room/Suite Physical Information

For each registered storage area, laboratory suite or room:
Include a floor plan for the suite or room where select agent and/or toxin is to be used or stored. Floor plan for each suite or room should include as applicable: points of entry and/or egress for personnel, locations of equipment [including but not limited to]: sink, eyewash, fume hood, freezer, refrigerator, floor drains, showers, incubator, centrifuge, animal caging, autoclave, Biological Safety Cabinet (BSC) including type (e.g., Class II, Type A2; Class III)], Heating Ventilation and Air Conditioning (HVAC) supply and exhaust vents, and cage washing area. A separate floor plan specifying airflow may also be requested.

For storage only area(s), proceed to Section 7.

Answer the following questions for each laboratory suite or room:

The following questions may not apply to all biosafety levels. The accompanying instructions detail which questions apply to each biosafety level according to the current edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL), the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules, and the American Society of Tropical Medicine and Hygiene Arthropod Containment Guidelines. If the question does not apply to the laboratory suite or room, check "No".

Section 6B - Safety Levels

- Should consider the current edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL) **containment recommendations for each select agent and toxin based on the entity's proposed work objectives.** The biosafety level of the laboratory where the select agent or toxin will be used should be **consistent with the BMBL guidelines.**

- The **NIH laboratory safety level** should be indicated for each laboratory area used for research involving the **construction and handling** of either recombinant DNA molecules or organisms and viruses that contain recombinant DNA (recombinant DNA as defined in the NIH Guidelines) in accordance with recommendations in the current edition of the BMBL.

Section 6B – Suite/Room Physical Information

1. This laboratory is operated at (check all that apply):

☐ BSL2	☐ NIHBL2	☐ NIHBL2-LS	☐ ACL3
☐ BSL3	☐ NIHBL3	☐ NIHBL3-LS	☐ ACL4
☐ BSL4	☐ NIHBL4	☐ NIHBL4-LS	
☐ ABSL2	☐ NIHBL2N		
☐ ABSL3	☐ NIHBL3N		
☐ BSL3Ag	☐ NIHBL4N		
☐ ABSL4			

List the resources/references used _____

2. BSCs and fume hoods are certified at least annually and records kept for at least three years. Yes☐ No☐

3. A sink is present in the laboratory for hand washing. Yes☐ No☐
   If yes, the hand washing sink is hands-free or automatically operated. Yes☐ No☐

4. An eyewash station is readily available. Yes☐ No☐

5. Liquid effluents originating from the laboratory are collected and heat or chemically treated for sterility prior to exiting the facility or entering a public sewage system. Yes☐ No☐
   If yes,
   a. Are the liquid effluents from the containment shower areas similarly treated for sterility? Yes☐ No☐
   b. Is the effluent decontamination system validated monthly with a bio-indicator? Yes☐ No☐

If BSL3Ag, BSL4 or ABSL4 is selected, proceed to Section 7.

6. Access to the laboratory is through two self-closing doors. Yes☐ No☐
   If yes, door(s) from the anteroom open inward to the laboratory? Yes☐ No☐

Section 7 – PI and Work Information

- Completed Section 7 (A, B, C and any required attachments) for **each PI**
  - If all information is identical, multiple PIs can be submitted on one Section 7 (includes strain/serotype info in 7B)

- Rationale:
  - Each PI provides objectives for select agent/toxin use and storage in Section 7A, B, C
  - Specialized work specific information (e.g., animals, rDNA, BSL4) in attachments, only complete if relevant

Section 7A – PI Information and Select Agent/Toxin Locations

This submission is:	☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:		Date:	

Section 7A – Principal Investigator (PI) Information and Select Agent and Toxin Locations

A complete Section 7 must be submitted for each PI. If separate PI's would result in an identical Section 7 being completed, multiple PI's can be listed in the header.

PI	Last Name:	First Name:	DOJ Number:
			Date of Birth:
			Tier 1 Access ☐

Select Agent/Toxin/Regulated Nucleic Acid	Location		Laboratory or Storage (Select one or both)		Laboratory Safety Level (Leave blank if storage only)
	Bldg	Suite/Room	Lab	Storage	
			☐	☐	
			☐	☐	
			☐	☐	

Suite Legend: (If Applicable)	Suite A = Rooms 1, 2, 3, 4

Section 7A Example

- **Example 4**: An entity will perform clinical diagnostic work using *Bacillus anthracis* Pasteur strain, excluded strains only of *Francisella tularensis*, *Yersinia pestis*, and ricin A-chain. This entity will transfer or destroy any samples confirmed as select agents or toxins within seven days of identification.

PI	Last Name: Nguyen	First Name: Mina	DOJ Number:
			Date of Birth: 06/30/1978
			Tier 1 Access

Select Agent/Toxin/Regulated Nucleic Acid	Location		Laboratory or Storage (Select one or both)		Laboratory Safety Level (Leave blank if storage only)
	Bldg	Rooms	Lab	Storage	
Bacillus anthracis (Pasteur strain)	PHL	Suite 4-93	X	X	BSL3

Suite Legend: (If Applicable)	Suite 4-93 = Rooms 4-89, 4-91, 4-93, and 4-95

Section 7A Example

- **Example 5**: An entity has two PI's performing the same work with SARS-associated coronavirus. Drs. Werner and Sun propagate SARS-associated coronavirus, modify viral genes, and test pathogenesis of these recombinant viruses in the natural host.

PI	Last Name: Werner	First Name: Jennifer	DOJ Number
			Date of Birth: 03/21/1962
			Tier 1 Access

PI	Last Name: Sun	First Name: Xie	DOJ Number:
			Date of Birth: 011/08/1973
			Tier 1 Access

Select Agent/Toxin/Regulated Nucleic Acid	Location		Laboratory or Storage (Select one or both)		Laboratory Safety Level (Leave blank if storage only)
	Bldg	Rooms	Lab	Storage	
SARS-associated coronavirus (SARS-CoV)	MSTB	Suite B28	X	X	BSL3, NIHBL3, ABSL3
Genomic material – SARS-associated coronavirus (SARS-CoV)	MSTB	615, 617	X	X	BSL2

Suite Legend: (If Applicable)	Suite B28 = Rooms B28A, B28B, B28C, B28D, B28E, and B28F

Section 7B – Strain or Serotype Info

- Separate strain/serotype information from 7A table
- May submit for multiple PIs (if applicable)
- Available in Excel format

SA GRAM 08/17/12

This submission is:	☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity name:			Date:
PI(s):	Jones		

Section 7B – Strain or Serotype Designation Information

Select Agent/Toxin/ Regulated Nucleic Acid	Strain or Serotype Designations	
Bacillus anthracis	Ames	
	Vollum	
Burkholderia pseudomallei	K96243	
Avian Influenza virus	A/Goose/Guangdong/1/96 (H5N1)	
	A/Vietnam/1203/2004 (H5N1)	
Botulinum neurotoxins	BoNT/A1	
Recombinant nucleic acids encoding botulinum neurotoxins	A1 BoNTA-LC+H(n)	
	BoNTA-LC+Belt	

Section 7C – Description of Work

This submission is:	☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:			Date:
PI(s):			

Section 7C – Description of Work

1. Provide the objectives of work for each select agent and/or toxin listed in Section 7A by agent/toxin and containment level(s), including a description of the methodologies or laboratory procedures that will be used. Include any work involving animals, arthropods or plants. Attachments 1-7 must be completed if appropriate for the work described. If no work is being performed with select agent and/or toxin, indicate "storage only". Attach additional sheets as needed.

Agent/Toxin	BSL	Objective of Work

- For **each** select agent/toxin listed, indicate the BSL and objective of work including regulated nucleic acids.
- Multiple select agents/toxins may be listed together if the BSL and objective of work are the same.
- The objective of work should include information or specific aims for the work expected to be conducted **within the 3 year approval period.**

Section 7C – Description of Work

2. Provide an estimate of the maximum quantities (e.g., number of Petri dishes or total volume of liquid media) and concentration of each organism grown at a given time (e.g., 2 - 250 ml flasks of 10^5 cfu/ml). If select agent will not be propagated, indicate "no propagation of agent". Attach additional sheets if needed.

Agent	Maximum Quantity/Concentration

3. Provide an estimate of the maximum quantity of functional toxin held by the PI at any one time (e.g., 500 mg, 100 ml x 100 ug/ul). Attach additional sheets if needed.

Toxin	Maximum Quantity

4. Equipment that may produce infectious agent or toxin aerosols (e.g., ultracentrifuge, flow cytometer, cell sorter, plate washer) is contained in primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory. Yes ☐ No ☐

5. Name(s) of Individual(s) responsible for inventory of select agent(s) and/or toxin(s):

Inventory record is reconciled: ☐ Annually ☐ Other (specify frequency)_____

6. Regulated nucleic acids as defined in 7 CFR 331.3, 9 CFR 121.3, 42 CFR 73.3 or 42 CFR 73.4 are held in long-term storage. Yes ☐ No ☐

Section 7C – Description of Work

9. Will work be performed with:

a. toxins or with agents that will be propagated and produce regulated amounts of toxins? Yes☐ No☐
If yes, complete Attachment 1 – Work With Toxins

b. regulated nucleic acids, genetic modification of select agents or toxins, recombinant/synthetic nucleic acids or recombinant/synthetic organisms? Yes☐ No☐
If yes, complete Attachment 2 – Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids or Recombinant/Synthetic Organisms

c. animals? Yes☐ No☐
If yes, complete Attachment 3 – Work with Animals

d. plants? Yes☐ No☐
If yes, complete Attachment 4 – Work with Plants

e. arthropods? Yes☐ No☐
If yes, complete Attachment 5 – Work with Arthropods

10. Will work be performed in:

a. BSL3Ag laboratory? Yes☐ No☐
If yes, complete Attachment 6 – BSL3Ag Laboratories

b. BSL4/ABSL4 laboratory? Yes☐ No☐
If yes, complete Attachment 7 – BSL4/ABSL4 Laboratories

Section 7C – Attachment List

- Complete for each PI's work (if applicable):
  - Attachment 1: Toxins
  - Attachment 2: Regulated Nucleic Acids, Genetic Modification of BSAT, rDNA/Synthetic DNA, Recombinant/Synthetic Organisms
  - Attachment 3: Animals
  - Attachment 4: Plants
  - Attachment 5: Arthropods
  - Attachment 6: BSL3-Ag Laboratories
  - Attachment 7: BSL-4 Laboratories

Attachment 2 – Work with Regulated Nucleic Acids (NA), Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic NA, Recombinant/Synthetic Organisms

This submission is: ☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:		Date:
PI(s):	**Laboratory Safety Level:**	

Attachment 2 – Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids, or Recombinant Synthetic Organisms

1. Will work involve possession, use, or transfer of the following?
   - a. Nucleic acids that can produce infectious forms of select agent viruses. Yes☐ No☐
   - b. Recombinant and/or synthetic nucleic acids that encode for the functional form(s) of any select toxins if the nucleic acids (i) can be expressed in vivo or in vitro or (ii) are in a vector or recombinant host genome and can be expressed in vivo or in vitro. Yes☐ No☐
   - c. Select agent viruses, bacteria, fungi or toxins that have been genetically modified. Yes☐ No☐

2. Will work involve the following with select agents and/or toxins:
   - a. Introduction and/or modification of genetic elements. Yes☐ No☐
   - b. Recombinant or synthetic nucleic acids. Yes☐ No☐
   - c. Recombinant or synthetic organisms. Yes☐ No☐
   - d. Reverse genetics system to produce infectious forms of select agent viruses, or any complete set of reagents that would allow rescue of infectious virus available for use by a PI at the entity. Yes☐ No☐

Attachment 2 – Work with Regulated Nucleic Acids (NA), Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic NA, Recombinant/Synthetic Organisms

3. Will a restricted experiment be performed as defined in 42 CFR 73.13, 7 CFR 331.13 or 9 CFR 121.13? Yes☐ No☐
   a. If yes, please indicate the type of restricted experiment:
      ☐ The introduction of, or selection for, drug resistance trait(s) into select agent organisms.
      List the agent(s) and the drug resistance trait(s):
      Select Agent _____ Drug Resistance Trait _____
      Select Agent _____ Drug Resistance Trait _____
      Select Agent _____ Drug Resistance Trait _____
      ☐ The deliberate formation of DNA containing genes for the biosynthesis of toxin lethal for vertebrates at an LD_{50} < 100 ng/kg body weight.
      List toxins _____
   b. Has this PI received approval from the APHIS Administrator or HHS Secretary for this restricted experiment? Yes☐ No☐

4. Will work involve possession, use or transfer of **a product of** a restricted experiment? Yes☐ No☐
   a. If yes, please indicate the type of restricted experiment product:
      ☐ Drug resistance trait(s) in select agent organisms.
      List the select agent(s) and the drug resistance trait(s) _____
      ☐ DNA containing genes for the biosynthesis of toxin lethal for vertebrates at an LD_{50} < 100 ng/kg body weight.
      List toxin(s) _____
   b. Has this PI received approval from the APHIS Administrator or HHS Secretary for this product of a restricted experiment? Yes☐ No☐

5. Will experiments involve the acquisition of increased/restored virulence (e.g., drug resistance, increased host range, enhanced transmissibility, infectivity, environmental stability) in select agents or toxins? Yes☐ No☐

Attachment 3 – Work with Animals

This submission is: ☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:		Date:
PI(s):		**Laboratory Safety Level:**

Attachment 3 – Work with Animals

1. Provide the select agent/toxin and species of animal to be used:

Select Agent / Toxin	Species of Animal	Route(s) of Administration

2. Are animals exposed to select agents or toxins by the aerosol route? Yes ☐ No ☐
   If yes, is the aerosol exposure equipment used within a primary containment device? Yes ☐ No ☐

- Additional questions regarding animal procedures, housing, and waste stream

Attachment 5 – Work with Arthropods

This submission is: ☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:		Date:
PI(s):	**Laboratory Safety Level:**	

Attachment 5 – Work with Arthropods

1. Work is performed with **field-collected** arthropods in a <u>diagnostic capacity only</u> for identification of select agents. Yes☐ No☐

2. Work is performed to experimentally inoculate or infect arthropods (any stages) with select agents. Yes☐ No☐
   If yes, complete questions 3-16.

3. Provide the select agent and species of arthropod used:

Select Agent	Species of Arthropod

- Information on arthropods not previously collected
- Questions from Arthropod Containment Guidelines

Attachment 6 – BSL3Ag Laboratories

This submission is: ☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:		Date:
PI(s):		

Attachment 6 – BSL3Ag Laboratories

1. Supplies, material and equipment enter and exit BSL3Ag areas only through an airlock, fumigation chamber, or interlocked and double-door autoclave, or shower. Yes☐ No☐

   For materials which are temperature sensitive, a gas sterilizer, pass-through liquid dunk tank, or a cold gas decontamination chamber are provided. Yes☐ No☐

2. Is a shower required when leaving the containment boundary Yes☐ No☐

3. Disposable materials are decontaminated by an approved method (check all that apply): Yes☐ No☐
   - ☐ Autoclaved
   - ☐ Chemical (disinfectant, concentration, and time) _____
   - ☐ Incineration _____
   - ☐ Other _____

4. All containment areas are designed, constructed and verified to function as a primary containment barrier. All walls are constructed slab-to-slab and walls, floors, and ceilings are sealed. All penetrations into the laboratory are sealed airtight to prevent escape of agents and to allow fumigation for biological decontamination. Yes☐ No☐

Attachment 6 – BSL3Ag Laboratories

5.	Differential pressures/directional airflow are monitored and alarmed (visually and audibly) to indicate system failure.	Yes☐	No☐
6.	There is HEPA filtration of all supply and exhaust air from the room(s), inner change room(s), and anteroom(s).	Yes☐	No☐
	If yes, all HEPA filters are certified annually.	Yes☐	No☐
7.	Laboratory procedure and design features include:		
	a. Personnel ingress and egress only through a series of rooms which includes a ventilated vestibule.	Yes☐	No☐
	b. A clean change room outside of the non-containment/containment boundary.	Yes☐	No☐
	c. Doors that define a containment boundary have compressible or inflatable gaskets.	Yes☐	No☐
	d. A shower room at the non-containment/containment boundary.	Yes☐	No☐
	e. A dirty change room within the non-containment/containment boundary.	Yes☐	No☐
8.	A second shower is required at the facility access control point before donning street clothing.	Yes☐	No☐
9.	Humane restraining devices are provided in large animal rooms. If yes, describe. Add additional sheets as needed.	Yes☐	No☐
10.	Necropsy rooms are sized and equipped to accommodate large animals. If yes, describe. Add additional sheets as needed.	Yes☐	No☐

Instructions for Completion of APHIS/CDC Form 1

- Instructions are a separate document – not part of Form 1
- **Application instructions** provide additional information for answering the questions
  - Refer to Guidance Documents when appropriate
- **Amendment instructions**
  - Updated for new sections and new information
  - Prompt user for other changes that may be associated with the request
- Document will have links
  - Link from Table of Contents or Amendment Reference Table
  - Amendment instructions link back to application instructions

Instructions for Completion of APHIS/CDC Form 1

- **Partial** Sections 3, 4, 7A
  - submit only the requested change(s) to registration

- Contain information regarding policy, ex:
  - Toxins
  - Requesting exclusions
  - Strain/serotype updates
  - When special approvals may be needed (e.g., 1918 influenza virus, agent/toxin used at lower containment level than BMBL recommends, chimeric viruses)

Request (Cover) Letters

- Submitted with all amendments and amendment updates
- Signed by RO/ARO or an email from RO/ARO's address
- **Detail all application/registration changes to be made**
  - All changes to Form 1 requested in letter
- Examples in *Instructions*

Please add Mike Smith to our registration as a laboratorian under PI Andrews, see attached Section 4A.

Please update Mike Smith's (C-MS-000000) role to ARO. Mike Smith is currently security risk assessment (SRA) approved at our entity and has an assigned role of laboratorian. Updated Section 1 including Mr. Smith is attached.

Please remove rooms 101, 102, 103 and 104 from Principal Investigator (PI) Jones. These rooms will continue to be used by other PIs and should not be removed from our overall registration.

Amendment Reference Table

Amendment type	Signed Cover Letter	Sections 1A-C	Section 2	Section 3	Sections 4 A-C	Sections 5A-D	Sections 6A-6B	Sections 7A-7C, Attachments
Personnel Amendments								
Addition/Reactivation RO Addition/Reactivation ARO	State changes. (a)	Updated 1A & B	Updated (RO only)					
Addition/Reactivation Owner/Controllers	State changes. (a)	Updated 1A only						
Addition/Reactivation of Laboratorian, Animal Care Staff	State changes (name, role). (a)				Updated 4A			
Addition/Reactivation of Support Staff	State changes (name, role). (a)				Updated 4B			
Addition/Reactivation of Unescorted Visitor	State changes (name). Signed letter from RO at home entity.				Updated 4C			
Addition/Reactivation of PI	Requires (a)				Updated 4A & C as needed			Section 7 for new PI
Removal of Personnel; Laboratorian, Animal Care staff, Support Staff, Visitor	Reason for removal							
Removal of RO Removal of ARO	Reason for removal. New RO must be appointed.	Updated 1A & B	Updated (RO only)					
Removal of Owner/Controller	Reason for removal	Updated 1A only						
Removal of PI	State disposition of agents, reason for removal.				Updated 4A & C as needed			Updated if a co PI
Updates to Names, Titles or Supervising PI for Laboratorian, Animal Care Staff, Support Staff, Unescorted Visitor	State changes				Updated 4A, B and/or C as needed			
Updates to PI Names	State changes				Updated 4A & C as needed			Updated 7A & attachment headers
Updates to RO/ARO/Owner Controller Name or Contact Information	State changes	Updated 1A & B						
Updates to Tier 1 access	State changes and reason for change	Updated 1A as needed			Updated 4A, B and/or C as needed			Updated 7A as needed

(a) Requires SRA Approval (b) Inspection may be required

First page of 2 page table

Amendment Example 1

Addition or Reactivation of Laboratorians or Animal Care Staff

To add or reactivate non-visiting Laboratorians or Animal Care Staff, submit the following documentation:

- ☐ Cover letter stating the name of the individual to be added or reactivated
- ☐ Signed and dated *Section 4A* with the individual being added or reactivated:
  - For reactivations, use the individual's previously assigned DOJ Number in the DOJ Unique Identifier Number column.
- ☐ Complete *Section 7C* if the individual will be responsible for inventory.

Additional Information

- **Once an individual is SRA approved, his/her DOJ number must be included on Section 4 (e.g., if updating the individual's job title).**
- **An individual is deactivated upon the request to remove the individual. In the event that an individual requires access approval in the future, the entity may request to reactivate the individual. Reactivated individuals will use their previously assigned DOJ number, and this number must be included in Section 4.**

Amendment Example 2

Removal of Suite/Room

It is important for entities to consider how the removal of a suite/room may affect other aspects of their registration (e.g., the room to be removed is the only registered location for a select agent/toxin or a PI) and submit updates to other sections of APHIS/CDC Form1 as needed.

To remove a suite/room, submit the following documentation:

- ☐ Cover letter specifying all changes and signed by RO.

  Note: A new Section 7A is not required for this change.
- ☐ Documentation that effective decontamination appropriate to the use of the suite/room has been performed. If you believe decontamination is not necessary, please provide a risk assessment and/or contact your designated representative.
- ☐ If removal of suite/room removes a select agent/toxin, see *Removal of a Select Agent/Toxin*.
- ☐ If removal of suite/room removes a PI, see *Removal of a Principal Investigator.*
- ☐ If personnel are being removed, see *Removal of Laboratorians or Animal Care Staff, Support Staff, or Unescorted Visitors*, *Removal of an RO/ARO*, or *Removal of a Principal Investigator* as appropriate.
- ☐ If a select agent/toxin is being transferred to a different PI at your entity (intra-entity transfer) and this PI is not registered for the select agent/toxin, an updated Section 7 adding this select agent/toxin will need to be submitted and approved before the receiving PI takes possession of the select agent/toxin.

Amendments for Registered Entities Associated with Laboratory Response Network (LRN)

- Which select agents and toxins to keep on registration
- May be able to remove agents/toxins based on
  - Work performed
  - Requirements of state or other

Registered Entities Associated with Laboratory Response Network (LRN)

Entity registered for Tier 1 BSAT – Remains registered for Tier 1 BSAT

No change to the registration necessary

Entity must meet Tier 1 requirements by effective date (April 3, 2013)

Registered LRN Entities

Entity registered for Tier 1 BSAT – Removes Tier 1 BSAT

Cover letter

- Submit request to remove agents. Possible addition of *B. anthracis* (Pasteur strain).
- Disposition of select agents/toxins removed
- Effective decontamination of suite(s)/room(s)

Updates to Form 1

- Section 3
- Section 7 (Section 7A and 7C)

Registered LRN Entities – Example

Entity registered for Tier 1 BSAT – Removes Tier 1 BSAT

LRN lab currently registered for *Bacillus anthracis,* Botulinum neurotoxins*, Francisella tularensis, Yersinia pestis, Burkholderia mallei, B. pseudomallei, Brucella abortus, B. melitensis,* and *B. suis,* **but does not wish to remain registered for Tier 1 BSAT** and does not possess the Tier 1 BSAT**.**

Section 3 updated to:

- *B. anthracis* (Pasteur strain)
- *Brucella abortus, B. melitensis, B. suis*

Registered LRN Entities

Entity registered for Tier 1 BSAT – Removes Tier 1 BSAT

Amendment must be submitted and approved prior to April 3, 2013 (recommend submission before or during January 2013)

Must destroy/transfer any diagnostic samples positively confirmed as Tier 1 BSAT (and any other select agent/toxin not on registration) within 7 days

Tier 1 BSAT require immediate reporting followed by a Form 4 within 7 days

New Definition: Restricted Experiments (RE)

- Section 13(b)(1): Experiments that involve the **deliberate transfer of, or selection for, a drug resistance trait** to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.
- Section 13(b)(2): Experiments involving the deliberate formation of **synthetic or** recombinant nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50]< 100 ng/kg body weight.

Effective December 4, 2012: Approval needed to conduct RE as defined above, as well as to possess **product resulting from** any RE [as defined in Section 13(a)].

Prior Approval for Restricted Experiments

Effective December 4, 2012, an entity must submit a written request to conduct a restricted experiment (new definition) or possess the product resulting from an RE.

If the request is approved by the Federal Select Agent Program, the entity must submit an amendment to their registration.

- **Cover letter:** approval for RE (new definition), or approval for product of RE
- **Section 7:** update PI's work objectives, check yes for Attach 2
- **Attachment 2:** complete question(s) regarding RE and/or products of RE, describe work objectives
- Additional information as requested by the Federal Select Agent Program

Restricted Experiments with **Select Agents** Requiring Federal Select Agent Program Approval Section 13(b)(1)

	Prior to 2/7/2003	2/7/2003 – 12/3/2012	12/4/2012 onward
Creation of drug(1) resistant select agent using recombinant technology	NO	YES	YES
Possession and/or use of drug resistant select agent that was created using recombinant technology	NO	NO	YES(2)
Creation of drug resistant select agent using passive selection	NO	NO	YES
Possession and/or use of a drug resistant select agent that was created using passive selection	NO	NO	YES(2)

(1) If such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.

(2) For any product of a restricted experiment that is not in the entity's possession prior to 12/4/2012. If the entity possesses the product prior to 12/4/2012, approval under Section 13(b)(1) is not required to continue to possess or to use the product.

Drug resistant select agents regardless of the method used to create are subject to Sections 3(c)(3)and 4(c)(3) as select agents that have been genetically modified.

Restricted Experiments with **Select Toxins** Requiring Federal Select Agent Program Approval Section 13(b)(2)

	Prior to 2/7/2003	2/7/2003 – 12/3/2012	12/4/2012 onward
Creation of a recombinant toxin(1) construct	NO	YES	YES
Possession and/or use of a recombinant toxin construct	NO	NO	YES(2)
Creation of synthetic DNA encoding a select toxin	NO	NO	YES
Possession and/or use of synthetic DNA encoding a select toxin	NO	NO	YES(2)

(1) Lethal for vertebrates at an LD_{50} < 100 ng/kg body weight

(2) For any product of a restricted experiment that is not in the entity's possession prior to 12/4/2012. If the entity possesses the product prior to 12/4/2012, approval under Section 13(b)(2) is not required to continue to possess or to use the product.

Recombinant and/or synthetic DNA encoding for toxin is subject to Section 3(c)(2).






Select Agent Program Workshop

November 2012

For more information, please contact the Select Agent Program

Telephone: 301-851-3300 (APHIS) or 404-718-2000 (CDC)

E-mail: ASAP@aphis.usda.gov (APHIS) or lrsat@cdc.gov (CDC)

Web: www.selectagents.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Select Agent Program.